Emerging Animal Disease Preparedness and Response Plan

U.S. Department of Agriculture
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CHAPTER 1. INTRODUCTION AND DEFINITIONS

1.1 Introduction

The purpose of this plan is to define the processes by which the Veterinary Services (VS) unit of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) will identify, evaluate, and respond to emerging diseases in animal populations, and the implementation of these processes as a VS core business practice. This plan will help VS respond effectively to emerging animal diseases by outlining processes to be used to determine appropriate response activities. The framework for this plan was outlined in 2014 in the APHIS concept paper, "Veterinary Services Proposed Framework for Response to Emerging Animal Diseases in the United States."

Emerging animal diseases have the potential to negatively affect animal health, public health, and trade. Examples of such disease occurrences in the United States in the past 20 years include porcine reproductive and respiratory syndrome, infectious salmon anemia, West Nile virus, and monkey pox virus. More recent examples include the emergence of Schmallenberg virus in Europe and porcine epidemic diarrhea virus in the United States.

Because of the unknown nature of emerging diseases, defining a specific response plan is not possible. Some emerging disease will be reported after an acute impact in a limited number animals; some will be recognized only after a longer term impact on animal health or production. VS plans to work with all stakeholders in implementing appropriate response measures to emerging diseases, with the understanding that emerging diseases – at least when first defined – are clearly different from listed foreign animal diseases. VS has established response plans for foreign animal diseases such as foot-and-mouth disease and highly pathogenic avian influenza.

VS has engaged in emerging disease detection and response as part of its major goals since the 1990's. The "VS: A New Perspective" document also includes the concepts of identification, analysis, and response to emerging diseases. Rapid detection and response to emerging diseases are critical to animal agriculture as some can spread rapidly, threatening the livelihood of producers and limiting their access to important markets.

Rapid response to emerging diseases can prevent or limit the negative impact to animal health, the economy, food security, and public health. In these cases, having useful situational animal health information can help agency policy makers and the public make informed decisions. VS has an extensive history of working with animal agriculture participants, academic institutions, and State animal health officials. VS intends to apply this collaborative approach to increase awareness of, detect, characterize, investigate, and respond to emerging disease threats as well as provide accurate information to all interested parties. VS will use the activities described in this plan to provide a solid scientific foundation for developing strategic interventions and informing the public of all appropriate actions.

The goals of this plan are to outline four core activities associated with detection and response to emerging animal diseases:

- 1) Undertake global awareness, assessment, and preparedness for animal diseases or pathogens not currently in the United States that may be of animal or public health concern or have trade implications;
- 2) Detect, identify, and characterize disease events;
- 3) Communicate findings and inform stakeholders; and
- 4) Respond quickly to minimize the impact of disease events.

A fifth goal, addressing recovery from the event, would include strategies that stabilize animal agriculture, the food supply, and the economy, and protect public health and the environment. These activities, including the <u>secure food supply plans</u>, are an extension of this plan and are not detailed here.

1.2 Purpose of Document

This plan provides strategic direction for VS at all levels to detect and respond to emerging animal diseases. It also defines communication activities and possible response measures for an emerging animal disease occurring in the United States.

1.3 Audience

This document is intended for Federal and State animal health officials and industry partners. It provides strategic guidance and outlines roles and responsibilities for detecting, reporting and responding to emerging animal diseases.

1.4 Authority

The Animal Health Protection Act (AHPA), 7 *U.S. Code* 8301 et seq., authorizes the Secretary of Agriculture to restrict the importation, entry, or further movement in the United States or order the destruction or removal of animals and related conveyances and facilities to prevent the introduction or dissemination of livestock pests or diseases. It authorizes related activities with respect to exportation, interstate movement, cooperative agreements, enforcement and penalties, seizure, quarantine, and disease and pest eradication. The Act also authorizes the Secretary to establish a veterinary accreditation program and enter into reimbursable fee agreements for pre-clearance abroad of animals or articles for movement into the United States.

1.5 Definitions

Emerging disease: A disease, infection, or infestation in domestic or wild animals that is a threat to terrestrial animals, aquatic animals, or humans, and meets one of the following criteria:

- An unknown agent that is causing disease, infection, or infestation in a herd/flock/premises and has the potential to result in a significant animal or public health impact, and applied diagnostic tests have yielded negative or non-definitive results; OR
- 2. A newly identified agent that is causing disease, infection, or infestation in a herd/flock/premises and has the potential to cause significant animal or public health impact, or is occurring in multiple herds/flocks/premises; OR
- 3. A previously identified or known pathogenic agent that has a change in epidemiology, such as:
 - a. Increased pathogenicity,
 - b. Expanded host range,
 - c. Change in geography of an agent with the potential to cause a significant animal or public health impact, or
 - d. Unexpected morbidity/mortality

Risk Identification Team (RI team): Group within the VS Center for Epidemiology and Animal Health that has the lead for monitoring the global animal health landscape for potential threats, assessing the risk posed by a possible emerging disease in the United States, and gathering information upon which to base the response.

VS Liaisons: VS Directors who are the first level of review for information assembled and analyzed by the RI team.

VS points of contact (POC). Subject matter experts designated within each group in VS to gather field-level data on possible emerging diseases for further analysis by the RI team.

CHAPTER 2. IDENTIFYING AND CHARACTERIZING GLOBAL AND DOMESTIC THREATS TO ANIMAL HEALTH

2.1 Global and Domestic Awareness and Assessment

The Risk Identification Team (RI team) within the USDA's Center for Epidemiology and Animal Health (CEAH) Risk Analysis and Risk Assessment (RIRA) unit is responsible for monitoring the distribution of animal diseases domestically and globally to identify potential threats to U.S. agriculture. The team works collaboratively with personnel across VS, with other Federal Government and Tribal agencies, industry, and stakeholders to identify and describe global emerging animal disease risks.

The RI team will identify and characterize animal disease risks using information from VS points of contact (POC), APHIS International Services, and other sources, including the following:

- U.S. Department of Homeland Security's (DHS) National Biosurveillance Integration Center
- Centers for Disease Control and Prevention (CDC)
- Inter-American Institute for Cooperation on Agriculture
- International Regional Organization for Plant and Animal Health
- Pan-American Foot and Mouth Disease Centre
- World Organization for Animal Health (OIE)
- Food and Agriculture Organization of the United Nations
- World Health Organization

Open-source information available from international agencies and organizations, various media outlets, and peer-reviewed scientific literature will be reviewed daily, to maintain a baseline situational awareness of animal health issues and disease events globally.

Domestically, the RI team uses information available from a variety of resources, including:

- National Veterinary Services Laboratories
- National Animal Health Laboratory Network, voluntary National Animal Health Reporting System (NAHRS)¹
- National Animal Health System Monitoring System surveys
- Mandatory reporting such as that required by the "Reporting, Herd Monitoring and Management of Novel Swine Enteric Coronavirus Diseases Federal Order"
- Data provided by VS certification and surveillance programs

With these systems and previously established relationships with accredited veterinarians; producers; livestock market operations; universities; State and Tribal animal health, public health and wildlife officials; and other Federal agencies. VS can access, share, and evaluate a broad scope of information.

¹ Until the National List of Reportable Animal Diseases is proposed and finalized in the Code of Federal Regulation, the NAHRS system remains the system for reporting diseases in the United States.

Additionally, several industry organizations have implemented systems to gather animal disease information. These commodities include swine (Swine Health Information Center) and equine (Equine Disease Communication Center). VS personnel serve as agency liaisons to these efforts, facilitating communication and collaboration.

2.2 Roles and Responsibilities Overview

Successful emerging disease response requires a collaborative effort among APHIS units, VS, State Animal Health Officials, and animal industries.

VS units. The responsibilities of units within VS is described in general here and further detailed throughout this document.

Science, Technology and Analysis Services (STAS). The RI team, part of CEAH's Risk Identification and Risk Assessment (RIRA) unit, is the primary unit responsible for monitoring domestic and international information sources described in section 2.1, conducting a preliminary evaluation of information pertaining to risks to U.S. animal health, and leading further analyses and data gathering when possible emerging diseases are identified. The team maintains a database of diseases being actively monitored and a time interval for updating information used to assign a risk level to each.

In addition to the RI team, STAS includes other units that will be involved in emerging disease assessment and response. The National Veterinary Services Laboratories (NVSL) regularly interacts with global and domestic animal health and research laboratories. NVSL Directors will designate POCs responsible for communicating knowledge of possible emerging diseases to RI team analysts and assisting with the collection and initial review of information and risk category assignment. In addition, NVSL will designate Directors to serve as liaisons to the RIRA Director to review information prepared by the RI team and their POCs and to assign appropriate subject matter experts within their unit to participate in cross-unit emerging disease teams.

Surveillance, Preparedness and Response Services (SPRS). As the VS unit responsible for implementation of VS surveillance, preparedness and response activities, SPRS staff routinely receive information on potentially emerging animal health issues. Emerging diseases POCs will be designated for each animal commodity, in the National Preparedness and Incident Coordination Center (NPICC), and in the One Health Coordination Center (OHCC). The role of the POC is to communicate information regarding potential emerging diseases to the Risk Identification analysts for situational awareness, to provide subject matter expertise to the RI team to determine a risk category assignment for each agent, and communicate issues up their respective supervisory chains.

In addition, Directors of the Avian, Swine and Aquatic Animal Health Center; Cattle Health Center; Sheep, Goat, Cervid and Equine Health Center; OHCC; and NPICC will serve as liaisons to the RIRA Director to review information prepared by the RI team and their POC on each global agent designated a risk category 3 or 4, domestic agent designated a risk category 1 or greater, or each agent where additional information is required before a risk category can be assigned. The VS liaisons will determine if additional information,

analyses, or field response is required, and will assign appropriate subject matter experts within their centers to participate in the cross-unit emerging disease team to evaluate these needs and make recommendations.

National Import and Export Services (NIES). POCs from NIES will inform the RI team of potential emerging diseases that need evaluation and by providing subject matter expertise to determine preliminary risk category assignments. NIES will also designate Unit Directors as liaisons to review information prepared by the RI team and to assign, as necessary, appropriate subject matter experts within their unit to participate in cross-unit emerging disease teams.

States. States' responsibilities include reporting under the NAHRS². However, States are encouraged to contact the appropriate VS Assistant Director with any unusual disease event in their state to discuss any results of diagnostic testing and available epidemiological information. Further state responsibilities would include issuance of holds or quarantines and participation in any monitoring, control, or eradication activity determined to be appropriate.

Industry. Previously established communication links with industry organizations will be used to communicate information, discuss response options, and address questions related to potential disease risks and concerns. For those industries that have implemented systems to gather animal disease information, such as the Swine Health Information Center and Equine Disease Communication Center, VS personnel serve as agency liaisons to these efforts, facilitating communication and collaboration.

Agency and Non-Agency Partners. Other Federal partners in USDA, DHS, CDC, U.S. Geological Survey, etc., as well as State Animal Health Officials, industry leaders, National Animal Health Laboratory Network laboratories, and accredited veterinarians, will provide information, review and subject matter expertise to the RI team, as needed, to help analyze information and determine the level of risk to US animal or public health posed by emerging diseases. Depending on the situation, partners may provide subject matter experts to participate in the cross-unit emerging disease teams to assist with evaluation and characterization of the disease incident, communications, and other related emerging disease response activities.

2.3 Initial Assessment of Information

- 1. When the RI team becomes aware of a possible emerging disease risk, the team will work with VS POC to conduct a preliminary analysis and assign the disease to a risk level category (Appendix A):
 - Level 1: Nominal risk to U.S. animal or public health
 - Level 2: Potential risk to U.S. animal or public health
 - Level 3: Impending risk to U.S. animal or public health
 - Level 4: Current risk to U.S. animal or public health
- 2. The RI team will write a briefing for international emerging disease risks designated at risk level 3, domestic diseases designated at any level, or diseases for which more information is needed before a risk level can be assigned.

² Until the National List of Reportable Animal Diseases is proposed and finalized in the Code of Federal Regulation, the NAHRS system remains the system for reporting diseases in the United States.

- 3. The RI team will share the briefings with appropriate VS Liaisons for review.
- 4. If, based on the results of the review, the severity and complexity of a disease incident warrants additional evaluation, characterization, or response. VS Liaisons will identify appropriate subject matter experts to form a cross-unit Emerging Disease Team to determine the additional information, analyses, or field response needed to thoroughly evaluate, characterize, or mitigate the disease incident (Appendix B).

2.4 Evaluation of Disease Incidents and Recommendations for Response

- 1. When the initial review of information by the RIRA Director and VS Liaisons determines an emerging disease incident requires further evaluation, characterization, or response, VS liaisons, in collaboration RI analysts and VS POC, will identify appropriate subject matter experts in APHIS to form a cross-unit Emerging Disease Team to conduct the evaluation. If the animal disease is associated with human health outcomes, subject matter experts in CDC will be identified to assist with the evaluation and development of recommendations.
- 2. The RI Team Lead will initially organize and lead the Team to review information, determine gaps in data or preparedness, and outline additional analyses, research, field epidemiological investigations, or mitigations needed to fully characterize and respond to the emerging disease incident.
- 3. The results of this evaluation, including any recommendations for response, will be documented and provided to VS Liaisons for presentation and decision making by the VS Executive Team (VSET). Recommendations will outline any regulatory issues or financial needs associated with each action.
- 4. The VSET will approve and authorize resources for the appropriate response measures. Depending upon the scale, scope, and urgency of the situation, the VSET may need to designate responsibility to the appropriate VS unit for each recommendation. For instance, further field investigations would be the responsibility of and coordinated through SPRS; pathway analyses would be the responsibility of and coordinated through RIRA or NIES; and questions about existing surveillance data would be coordinated through and by STAS.

CHAPTER 3. RESPONSE COORDINATION

After an evaluation of an emerging disease incident has been completed, and the recommendations include response options, the cross-unit Emerging Disease Team will take the lead in coordinating the response option(s) assigned by the VS Executive Team. The actions necessary to develop and implement specific responses are outside the scope of this document. However, standard program, regulatory, and budgetary business practices will be followed and will include, as needed, the use of VS Guidance 12001.2 as well as response evaluation tools such as the "Technique for the Assessment of Intervention Options" (TAIO) and Decision Lens.

If the emerging disease impacts a single species, then the appropriate SPRS Commodity Center Director (or their designee) will become the leader of the cross-unit Emerging Disease Team and will be responsible for developing and implementing response options. If a disease impacts more than one commodity, then it will be the responsibility of the SPRS Associate Deputy Administrator to designate a leader for the team. The team leader may request further analyses to clarify response options. Aspects to be considered include impacts to international trade, animal health, public health, food security, agricultural production, and the environment; geographic distribution of disease; political pressures; resource intensity; available subject matter expertise; diagnostic capabilities; regulatory authorities; and the potential for bioterrorism.

Possible responses are listed by risk category below and will depend on the specific situation. Additionally, there may be responses not identified in the document that might be relevant to a certain emerging disease incident.

3.1 Possible Responses to Emerging International Threats

Risk Level 1 (Nominal Risk to U.S. Animal or Public Health):

• Provide continual monitoring of emerging disease incident and situational awareness updates, as needed

Risk Level 2 (Potential Risk to U.S. Animal or Public Health):

- Continue to monitor emerging disease incident and provide situational awareness updates, as needed
- Assess preparedness status for introduction (e.g. presence of valid diagnostic tests, vaccines)

Risk Level 3 (Impending Risk to U.S. Animal or Public Health) or insufficient information available to assign to a risk level

- Work with APHIS International Services personnel in relevant countries to get additional information on disease incident
- Determine need for further evaluation and characterization of incident by an Emerging Disease Team
- Conduct pathways and import risk assessments, and determine data gaps and needs for additional information to inform high risk entry points
- Implement import restrictions or increased surveillance, as needed

 Develop and distribute communication materials to relevant partners and stakeholders

3.2 Possible Responses to Emerging Domestic Threats

Risk Level 1 (Nominal Risk to U.S. Animal or Public Health):

- Contact diagnostician(s), State and Federal partners, and relevant diagnostic laboratories to get additional information and confirmation of disease incident
- Identify needs for and conduct additional research (e.g., animal inoculation studies, additional molecular characterization of pathogen)
- Determine reservoirs, transmission pathways and potential impacts on U.S. animal or public health
- Implement increased surveillance, as needed
- Conduct an investigation on farms meeting an epidemiological or disease based case definition, as needed to characterize incident
- Develop and distribute communication materials to relevant agency and non-agency partners and stakeholders
- Increase diagnostic capacity, as needed

Risk Level 2 (Potential Risk to U.S. Animal or Public Health):

- All options in Level 1
- Increase laboratory diagnostic capacity and evaluation or development of effective vaccines
- Provide guidance to States, industry, and stakeholders for prevention, detection, and response to emerging disease

Risk Level 3 (Impending Risk to U.S. Animal or Public Health):

- All options in Levels 1 and 2
- Develop a case definition for reporting
- Determine need for and establish regulations and/or new policy

Risk Level 4 (Current Risk to U.S. Animal or Public Health):

- All options in Levels 1-3
- Conduct active surveillance (situational dependent) and develop a surveillance plan
- Conduct analytical epidemiologic investigations
- Determine need for and establish regulations for a new program (certification, control, or eradication) or new policies

CHAPTER 4. COMMUNICATION AND INFORMATION SHARING

Throughout the process of developing an emerging disease response, situational awareness and risk assessment information, including the results of disease incident evaluation and characterization, will be shared with States, Tribes, affected industry and other government agencies such as Food and Drug Administration, Food Safety Inspection Service, CDC, and stakeholders. These will be shared in writing and will include the use of Stakeholder Registry Notices that can be further distributed by e-mail to the States, impacted industry associations, and other Federal partners. If a determination is made that a disease poses an actionable threat, VS will engage the National Assembly of State Animal Health Officials, American Association of Veterinary Laboratory Diagnosticians, industry associations, and industry emerging disease groups as appropriate to develop response options. Formal USDA communications around specific response activities, such as investigative studies, eradication, control, or certification programs will be coordinated with APHIS Legislative and Public Affairs.

Communication and collaboration among those government agencies, industries, and stakeholders impacted by a potential or emerging disease is essential to ensure a timely and appropriate response. Communication should flow in both directions to ensure that information is current and analyses/evaluations are well vetted and accurate. This communication, collaboration and information sharing needs to be continuously occurring, allowing emerging diseases to be detected early. These communications will be varied depending on the situation, but will include both written and verbal methods.

It is important to stress that any emerging disease information released by the USDA will maintain the confidentiality of any individual owner.

4.1 Communication within USDA

4.1.1 Situational awareness documentation

A written emerging disease brief summarizing available information and risk level assignment will be prepared by the RI team and VS POCs as needed (see section 2.3). These summaries will be provided to VS liaisons for discussion during regularly scheduled meetings or ad hoc meetings based on the urgency of the situation. Briefs may be further distributed internally and discussed during regularly scheduled VS internal conference calls.

4.1.2 Summary of evaluation and characterization of disease incidents with recommendations for response

When review of emerging disease briefs and other information results in a further evaluation of an emerging disease incident by an Emerging Disease Team, a summary of the evaluation and recommended response options will be provided to VSET for review and decision-making during regularly scheduled weekly or monthly meetings, or during ad hoc meetings as needed based on the urgency of the situation.

4.2 Communication with Federal Partners, State and Industry

VS liaisons are responsible for distributing written situations reports of the emerging disease incident to Federal, State and industry partners. In addition to written notices, conference calls, webinars or face-to-face meetings may be required. The situation report will be updated as appropriate and distributed as additional information becomes available.

4.3 Public Communication

Public communication will be handled at various levels and through multiple written and/or verbal methods. Stakeholder announcements and FAQ websites are a few of the tools that may be utilized. Not all emerging diseases will warrant public communication.



APPENDIX A: Guidance for Assigning Diseases to a Risk Level

Threat Definitions

	Host Range	Pathogenicity	Current Geographic Range	
			Has not been identified in the U.S. within last year	Disease confirmed in the U.S.
Minimal	Restricted to a single, non-livestock species and/or wildlife species with no public health concerns	Low morbidity/mortality	Local presence in a foreign country with no transboundary spread	Small local presence with no spread, and no recognized high risk transmission pathways
Moderate	Single agricultural commodity and/or a new host species recognized	Moderate morbidity/mortality, or potential to affect public health	Present in a foreign country with minor to moderate spread to neighboring countries or regions	Local presence with limited spread to surrounding counties/parishes, or recognized high risk transmission pathways for spread
Significant	One or more agricultural commodities and/or zoonotic transmission risks	High morbidity/mortality or significant risk to public health	Present in a foreign country bordering the US, or trading partner with a recognized high risk transmission pathway	Multiple emergence points or regional spread recognized

Using Threat Definitions to Assign Diseases to Risk Levels³

Level 1—Nominal risk to US Animal or Public Health:

- Host Range: Minimal to moderate host range for diseases not recently identified in U.S.; minimal host range for diseases confirmed in the U.S.
- Pathogenicity: Minimal to moderate
- Current geographic range: Minimal geographic range for diseases confirmed in the U.S.; minimal to moderate geographic range for diseases not recently identified in U.S.

Level 2—Potential risk to US Animal or Public Health:

- Host range: Moderate to significant host range for diseases not recently identified in U.S.; moderate host range for diseases confirmed in the U.S.
- Pathogenicity: Moderate to significant
- Current geographic range: Minimal geographic range for diseases confirmed in the U.S.; minimal to moderate geographic range for diseases not recently identified in the U.S.

Level 3—Impending risk to US Animal or Public Health:

- Disease not recently identified in the U.S.
 - o Host range: Significant
 - o Pathogenicity: Moderate to significant
 - o Current geographic range: Significant
- Disease confirmed in the U.S.
 - o Host range: Moderate

³Threat Definitions and Risk Levels are qualitative, and assignment of individual emerging animal diseases may vary, based on the information available.

Pathogenicity: Moderate to significantCurrent geographic range: Moderate

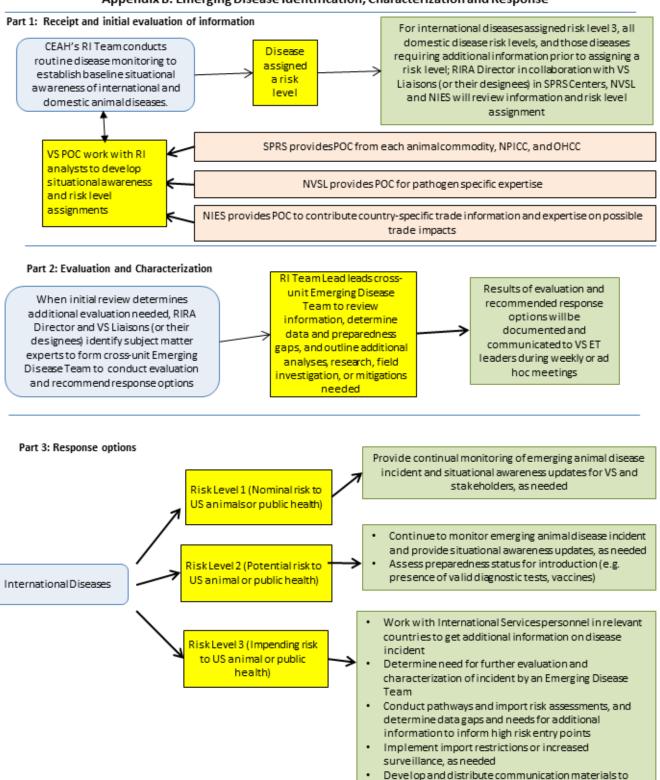
Level 4—Current risk to US Animal or Public Health:

• Host range: Significant

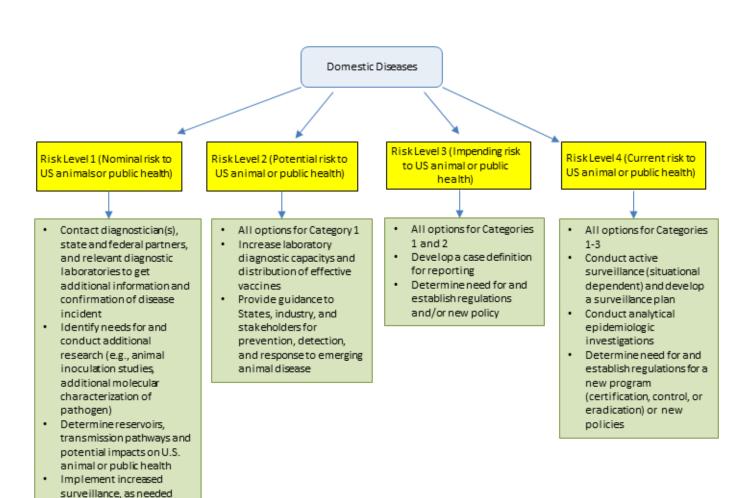
- Pathogenicity: Moderate to significant
- Disease confirmed in U.S. with moderate to significant geographic range



Appendix B: Emerging Disease Identification, Characterization and Response



relevant partners and stakeholders



Acronyms

stakeholders Increase diagnostic capacity, as needed

- CEAH: Center for Epidemiology and Animal Health
- · RI: Risk Identification

 Conduct an epidemiological investigation, as needed to characterize incident
 Develop and distribute communication materials to relevant agency and non-agency partners and

- · POC: Points of Contact
- · RIRA: Risk Identification and Risk Assessment Unit
- · SPRS: Surveillance, Preparedness and Response Services
- NPICC: National Preparedness and Incident Coordination Center
- · OHCC: One Health Coordination Center
- NVSL: National Veterinary Services Laboratories
- NIES: National Import Export Services
- VS ET: Veterinary Services Executive Team